QUESTIONS AND ANSWERS

1. What is the department's stance on ISBT? Will it be a mandatory state requirement? Does the state have a specific timeline? Will an implementation plan be required for the next inspection round or do you have a specific timeline for implementation plans?

State Regulation: N.J.A.C. 8:8-8.8 (a) requires that labeling of blood shall be consistent with the most recent Code of Federal Regulations. As you already know, the final rule of the FDA for labeling drugs including blood and blood components entitled: Bar Code Label Requirements for Human Drug Products and Biological Products was published on February 26, 2004 in the Federal Register (69 Federal Register 9120) with an effective date for compliance of April 26, 2006.

The regulation for blood and blood components can be found in the 21 CFR 606.121(c)(13) requiring that the blood container label must bear encoded information in a format that is machine-readable and approved for use by the Director, Center for Biologics Evaluation and Research. That means that any blood or blood component label with the possibility of being transfused to a patient, whether or not it is actually transfused must be labeled in that manner including syringes when it is used to aspirate or extract blood or blood components from a blood container for transfusion to neonates.

YES, the state regulation for labeling blood and blood products is consistent with the FDA‘s requirement including its effective date for compliance which is April 26, 2006.

The state regulation can not be less stringent than the FDA so the State can not give you an extension nor exception to the FDA rule since it is not a rule promulgated by the State.

If you can not comply with the FDA labeling requirement, you have to request from CBER an exception or alternative, and not from the State.

However during inspection, we will not cite non compliance with ISBT as deficiency but we will comment whether you have complied with the ISBT or not in our report (as long as the blood bank follows the Uniform Labeling of 1985).

2. What is the philosophy behind a state inspection? Is it process oriented ie. AABB, FDA or is it a record review looking for dotted I's and crossed t's? Will the state consider creating a checklist for the inspection like the AABB has for inspectors? It can be used by the facilities to do internal audits. Will the state consider doing a checklist of new changes in the regulations that can be used by the facilities to highlight areas of difference?

d) All of the above.

- To ensure the provision of blood bank services that protect the health and safety of blood donors and recipients.

- Compliance with applicable state and federal rules and regulations and AABB Standards.

- Quality Assurance

- Education

- When necessary Enforcement Action

    -Failure to correct deficiencies

    -Serious deficiencies which jeopardize patient health and safety

The state inspection is definitely “process oriented” also. During inspections, we look at a set of related tasks and activities to accomplish a work goal just like the AABB and the FDA. We review your SOP if adequate, blood bank records and quality control/assurance programs, staff training and competency records and direct observation of staff’ performance. We review root cause analysis and corrective action plans that the facility used to correct deficiencies and errors and assess whether the corrective action plan prevents recurrence.

However, this does not mean that blood bank will not be cited when the evaluators find typos, questionable or inaccurate records. N.J.A.C. 8:8-5.1 requires the blood bank to maintain suitable and legible records of every significant step of the process and to make proper correction to errors made in the records. If evaluators are finding errors in the records, it may indicate that blood bank records are not reviewed by the supervisor or the director as required by N.J.A.C. 8:8-4.1 (QC and QA Programs) or that staff on the floors have not been adequately trained to complete forms correctly.

YES, the State will make a checklist to be used for inspection and we also brought with us a summary of the significant changes in the revised blood bank regulations.

3. What is the state's role in assuring an adequate blood supply during a disaster? Will the state take the lead role in planning and response or should such planning and response be done by the blood centers in conjunction with national entities like ABC, BCA, and NBE?

State’s role

- Determination of health issues/risks

- Communication

- Coordination
- Encourage blood donation
- Defer elective surgery
- May waive donor collection requirements

4. What is the state's plan for avian flu virus? Will elective surgical procedures be stopped in order to lessen demand in light of declining collections within the state? Will there be strategic planning sessions now or in the near future?

Role of NJDHSS

- Planning and Coordination
- Surveillance and investigation of avian flu in New Jersey
- Provide guidance to Local Health Department and Local Information Network and Communication Systems (LINCS) agencies in the development of pandemic plans
- Provide guidance to other public health care partners regarding their roles related to an influenza pandemic communication to public

May Include:

- Call for healthy donors to address blood shortage
- Request or directive to hospitals to defer elective surgery
- Donor deferral issues unknown at this time
- Quarantine under Emergency Health Power Act

Incorporated Slides (Pandemic)

5. With regards to transfusions, are there any regulations which define how soon after the completion of the transfusion the final set of vitals should be recorded? Does this change with a transfusion reaction and if so how? With regard to a transfusion reaction, is it acceptable to define a febrile reaction as a 2^{O} F rise in temperature resulting in a temperature of 100^{O}F or greater. This would allow a 2 degree rise in a post-op hypothermic patient with a warming blanket where the 2 degree rise to 99^{O}F may be attributed to the blanket.

There are no regulations which specify “how soon after the completion of the transfusion the final set of vitals be recorded.

The AABB Standard only requires recording of pre- and post transfusion vital signs (AABB 5.19.6) while the state regulation requires recording of pre-, 15 minute after the start of the transfusion and the post transfusion vital signs.

The AABB also defines for surveillance purpose a rise of 1^{o} C or 2^{o} F as one of the symptoms typically associated with an acute transfusion reaction that needs to be investigated if it occurs at the time of the transfusion.

Both the state regulation and the AABB Standard refers to “pretransfusion” vital signs which the State interprets as the vital signs taken immediately before the start of the transfusion and post transfusion vital signs as vital signs taken immediately after the blood transfusion is completed. Consequently, a 1^{o} C or 2^{o} F rise from the pre transfusion vital signs need to be investigated for suspected transfusion reaction unless the patients are post op who can have false elevation of 2 degree Fahrenheit from being covered with a blanket in the Operating Room.

This question was already posed to us before and as long as you document on the transfusion record that it is an OR patient, the physician knew about the increase in temperature and no other signs and symptoms of a suspected reaction are exhibited with the 2 degree Fahrenheit rise in temperature, a transfusion reaction investigation is not required.

6. What are the qc requirements for a heat sealer and their frequency? Does a qc date label need to be affixed to the instrument.

We can not find the qc requirements for heat sealer so we contacted Gambro, one of the manufacturers for this equipment and we were told that its product Terumo Seal Safe only requires an annual preventive maintenance by qualified service technician, cleaning and observation if seals are properly functioning each day of use.

As you know, the state, FDA and the AABB Standards require that all blood bank equipment be assigned a unique identification number and the FDA also requires the equipment to be validated for its intended use.

The State regulation requires all equipment to be identified with a unique identification number but it does not require the qc date label to be affixed on the instrument as long as you have records that the required QC for the equipment was performed and is traceable.

7. Does a blood donor need to initial changes on the donor registration form in addition to the usual staff documentation?

Yes, our experience in inspection indicated that if we allow the donor staff to document the changes on the donor history for the donor, we can not be assured that the corrected responses were completed before the donor was allowed to donate or at a later time. So many times if this practice is allowed, the historians are not as careful in ensuring that the donor histories are properly reviewed before blood collection causing blood to be quarantine until donor is contacted.

The State (just like the FDA and the AABB Standards) requires that **on the day of donation**, the prospective donor's history shall be evaluated and the donor examined by qualified blood bank personnel trained to follow guidelines acceptable to the Department in order to determine that blood donation will not be detrimental to the donor and to determine that the donor has no evidence of disease transmissible by blood transfusion.

We do not anticipate the requirement for obtaining the donor's initial whenever the donor makes additions or corrections to the donor history a problem since the donor is still available to initial in the presence of the historian after the historian verifies the response given by the donor before the actual blood donation.

N.J.A.C. 8:8-5.1 (Records) requires each significant step steps of the process and who performed them.

8. In documents which require Medical Director review, is it acceptable to document the supervisor's or manager's preliminary review with initials, month and year rather than initials, month, day, and year?

No. it needs to be completed with month, day, and year. N.J.A.C. 8:8-5.1 (Records) requires each significant step steps of the process to be documented and who performed them. "Significant step" means any step that would be necessary to reconstruct, from the record alone, the procedures performed and who performed them.

9. New York State now allows 16 year olds to donate. Does the New Jersey Department of Health plan on following suit? What type and how many data points will be needed for the department to consider lowering the age limit?

It took us the Department more than 5 years to lower the age of donation without parental consent from 18 years old to 17 years old. So it will not be as easy to propose such a change. However we will be happy to receive statistics from the state of NY in its experience in allowing 16 years old to donate and the impact to blood donation.

10. Could the state consider the possibility of having deviations reported electronically, similar to the FDA?

YES, we will advise as soon as we are capable of accepting electronic reports for error/accident and transfusion reaction incidents.